PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—Astringent Drug Products

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 58 FR 54462, Oct. 21, 1993, unless otherwise noted.

Subpart A—Astringent Drug Products

§ 347.1 Scope.

(a) An over-the-counter skin protectant drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 347.3 Definitions.

As used in this part:

(a) *Astringent drug product* means a drug product that is applied to the skin or mucous membranes for a local and limited protein coagulant effect.

(b) [Reserved]

§ 347.10 Astringent active ingredients.

The active ingredient of the product consists of any one of the following within the specified concentration established for each ingredient:

(a) Aluminum acetate, 0.13 to 0.5 percent (depending on the formulation and concentration of the marketed product, the manufacturer must provide adequate directions so that the resulting solution to be used by the consumer contains 0.13 to 0.5 percent aluminum acetate).

(b) Aluminum sulfate, 46 to 63 percent (the concentration is based on the anhydrous equivalent).

(c) Witch hazel.

[58 FR 54462, Oct. 21, 1993, as amended at 59 FR 28768, June 3, 1994]

§ 347.50 Labeling of astringent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an ''astringent.''

(b) *Indications.* The labeling of the product states, under the heading ''Indications'' any of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph (b) may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing aluminum acetate identified in § 347.10(a).* ''For temporary relief of minor skin irritations due to'' (select one or more of the following: ''poison ivy,'' ''poison oak,'' ''poison sumac,'' ''insect bites,'' ''athlete's foot,'' or ''rashes caused by soaps, detergents, cosmetics, or jewelry'').

(2) *For products containing aluminum sulfate identified in § 347.10(b) for use as a styptic pencil.* ''Stops bleeding caused by minor surface cuts and abrasions as may occur during shaving.''

(3) *For products containing witch hazel identified in § 347.10(c).* (i) ''For relief of minor skin irritations due to'' (select one or more of the following: ''insect bites,'' ''minor cuts,'' or ''minor scrapes'').

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) ''For external use only. Avoid contact with the eyes.''

(2) *For products containing aluminum acetate identified in § 347.10(a) or witch hazel identified in § 347.10(c).* ''If condition worsens or symptoms persist for more than 7 days, discontinue use of the product and consult a'' (select one